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reasonably convey the claimed invention to one skilled in the relevant art that the Applicant, at the time the application was filed, had possession of the claimed invention.

Independent claim 7 recites a "locking element being moveable without deformation from an initial position that permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that retains at least two bone screws to said implant." Independent claim 42 recites "a non-elastic locking element for locking at least two bone screws inserted in said at least two bone screw receiving holes." Independent claim 47 recites "at least a portion of said locking element being adapted to cover at least a portion of at least one of said bone screw receiving holes and being rigid." As discussed below, a locking element being moveable without deformation (as recited in independent claim 7), a non-elastic locking element (as recited in independent claim 42), and at least a portion of a locking element being rigid (as recited in independent claim 47) are fully supported by Applicant's specification.

Applicant's specification discloses that "[t]he plate and its component parts, may be made of any implant quality material suitable for this purpose and suitable for use in the human body, such as, but not limited to, titanium or its alloys." (Specification, page 4, lines 17-19.) Accordingly, because the locking elements are component parts of plates (or implants as recited in independent claims 7, 42, and 47), Applicant's specification discloses that the locking elements can be made of titanium or its alloys.

Additionally, Applicant's specification discloses various embodiments of the locking elements. For example, Applicant's specification discloses an embodiment of a locking element (e.g., 20) that is "rotated in the clockwise direction" to "positively lock the associated bone screws 30" in place. (Specification, page 22, lines 22-26; and FIG. 11.) Furthermore, Applicant's specification discloses "embodiments of locking elements 20a-20d" which "may be rotated in the direction of arrow A to bear upon at least a portion of the screw head to lock the bone screws to the plate." (Specification, page 25, lines 15-20; and FIGS. 31A-31D.) However, Applicant's specification also discloses an embodiment of a locking element where "the locking element head 23 can be provided with two slits 42 for providing flexibility to the locking element head 23 to assist in the locking element's ability to ride over the top of the bone screw head 32 during the

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locking action when the locking element is rotated." (Specification, page 22, lines 18-21; FIG. 16.) As such, the slits 42 are provided to afford flexibility of the locking element head 23, and, in doing so, allow the associated locking element to deform when moved from an initial position to a final position. Hence, the locking elements without the slits 42 (such as the locking elements 20 and 20a-20d) are not flexible, and, necessarily, would move without deformation from the initial position to the final position. Accordingly, Applicant submits that the specification discloses locking elements that are non-deformable, non-elastic, and/or rigid.

Given that Applicant's specification discloses locking elements that can be made of titanium or its alloys, and that can be non-deformable, non-elastic, and/or rigid, independent claims 7, 42, and 47 are fully supported by Applicant's disclosure. That is, Applicant's specification fully supports a locking element being moveable without deformation (as recited in independent claim 7), a non-elastic locking element (as recited in independent claim 42), and at least a portion of a locking element being rigid (as recited in independent claim 47). Accordingly, Applicant submits that the Examiner's rejection of claims under 35 U.S.C. § 112, first paragraph, has been overcome.

## **II. 35 U.S.C. § 103(a) Rejections**

The Examiner rejected claims 7-10, 13-16, and 18-51 (including independent claims 7, 42, and 47) under 35 U.S.C. § 103(a) based on U.S. Patent No. 2,825,329 to Caesar ("Caesar"); and rejected claims 7-41 (including independent claim 7) under 35 U.S.C. § 103(a) based on U.S. Patent No. 4,488,543 to Tornier ("Tornier"). As discussed below, Applicant respectfully traverses these rejections. Furthermore, Applicant notes that in making these obviousness rejections, the Examiner did not consider the elements of Applicant's independent claims 7, 42, and 47 that were being rejected under 35 U.S.C. § 112, first paragraph. However, because the rejection under 35 U.S.C. § 112, first paragraph, has been overcome above, all elements of independent claims 7, 42, and 47 must be given patentable weight.

Recently, in KSR International Co. v. Teleflex Inc. et al., the Supreme Court reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) as set forth

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in Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). (See KSR v. Teleflex, 127 S.Ct. 1727 (2007).) Under Graham v. John Deere, the question of obviousness is resolved on the basis of factual determinations including (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (Graham v. John Deere, at 17-18, 148 U.S.P.Q. at 467.) However, even under Graham v. John Deere, a combination of references that does not teach or suggest each and every element of the claimed invention, or references that teach away from the claimed invention support a finding of nonobviousness. As discussed below, Caesar and Tornier both do not teach each and every element, and, in fact, teach away from the claimed invention.

Independent claims 7, 42, and 47 each recite a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." In rejecting independent claims 7, 42, and 47 under 35 U.S.C. § 103(a), the Examiner contends that a sterile package containing plates 140 and 150 "in effect would 'couple' the elements together prior to surgery." (Office Action, page 4, lines 3-8.) Merriam-Webster's Online Dictionary defines "couple" as "to connect for consideration together" and "to fasten together." (See <http://www.merriam-webster.com/dictionary/couple>.) Applicant submits that placing a plate and a locking element into a sterile package does not "connect" nor "fasten together" the plate and the locking element. Furthermore, as discussed below, Caesar and Tornier do not teach or suggest a locking element being coupled to the implant prior to the insertion of the bone screws.

Caesar discloses a second plate 150 attached to a plate 140 using bone screws 158 during surgery. To attach the second plate 150 and the plate 140 to one another, the bone screws 158 are first inserted into openings 156 in the second plate 150, then inserted into openings 70a and 72a formed in a bone, and, thereafter, received in openings 146 formed in the plate 140. (See Caesar, col. 3, lines 7-19; and FIG. 1.) Accordingly, Applicant submits that the second plate 150 and the plate 140 are attached to one another as a result of, not prior to, the insertion of the bone screws 158 into the openings 156 of the second plate 150 and the openings 146 of the plate 140.

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As such, unlike independent claims 7, 42, and 47, Caesar does not teach or suggest a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes," as recited in independent claims 7, 42, and 47.

Furthermore, Applicant submits that Caesar actually teaches away from the claimed invention as recited in independent claims 7, 42, and 47. As discussed above, the second plate 150 is attached to the plate 140 only after bone screws 158 are inserted into the openings 156 of the second plate 150 and into the openings 146 of the plate 140. Since Caesar expressly teaches that plate 150 is attached to plate 140 using the bone screws 158, Caesar teaches away from coupling a locking element to an implant prior to the insertion of the bone screws into the bone screw receiving holes. Therefore, because Caesar does not teach or suggest each and every element, and, in fact, teaches away from the claimed invention, Applicant submits that the Examiner's rejection of independent claims 7, 42, and 47 based on Caesar cannot be maintained. As such, the Examiner's rejection of claims 7-10, 13-16, and 18-51 under 35 U.S.C. § 103(a) based on Caesar has been overcome.

Tornier teaches a disc 11 that "has centrally between the three holes a diameter which partially covers each of heads 3a of screws 3 to assure their being held in corresponding holes 6." (Tornier, col. 2, lines 37-40.) Since the disc 11 covers the heads 3a of the screws 3, Applicant submits that the disc 11 of Tornier is attached to the plate 2 after the insertion of the bone screws 3 into the bone screw receiving holes 6. Tornier also teaches that the disk 11 "is elastic thereby making possible the passage of heads 3a of screws 3 and the backward movements of the screws 3, in the event that they come in contact with the cortical of the femoral head." (Tornier, col. 2, lines 44-48.)

As discussed above, independent claim 7 recites a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." Furthermore, independent claim 7 recites a locking element "being moveable without deformation from an initial position that permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that retains at least two bone screws to said implant." Given that the disc 11 of Tornier is coupled

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to the plate 2 after the insertion of the screws 3 into the bone screw receiving holes 6 and that the disc 11 is elastic, Tornier (unlike independent claim 7) does not teach or suggest both (1) coupling a locking element to an implant prior to the insertion of the bone screws into the bone screw receiving holes and (2) moving a locking element without deformation from an initial position that permits the insertion of at least one bone screw into the bone screw receiving holes to a final position that retains at least two bone screws to the implant. Furthermore, because the disc 11 is coupled to the plate 2 after the insertion of the bone screws 3 into the bone screw receiving holes 6, Tornier, like Caesar, actually teaches away from the claimed invention of independent claim 7. Therefore, because Caesar does not teach or suggest each and every element, and, in fact, teaches away from the claimed invention, Applicant submits that the Examiner's rejection of independent claim 7 based on Tornier cannot be maintained. As such, the Examiner's rejection of claims 7-41 under 35 U.S.C. § 103(a) based on Tornier has been overcome.

Applicant submits that independent claims 7, 42, and 47 are patentable over the Examiner's rejections under 35 U.S.C. § 103(a), and that claims 8-41, 43-46, and 48-51 are allowable at least because these claims depend from an allowable independent claim, or claims dependent therefrom.

### **III. Double Patenting Rejections**

The Examiner rejected claims 7-51 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-173 of U.S. Patent No. 6,193,721 ("721 patent"), claims 1-39 of U.S. Patent No. 6,936,051 ("051 patent"), and claims 1-117 of U.S. Patent No. 6,398,783 ("783 patent"), in view of U.S. Patent No. 5,468,242 ("242 patent"). The Examiner provisionally rejected claims 7-51 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-72 of copending U.S. Patent Application No. 10/926,734 ("734 application") and claims 1-62 of copending U.S. Patent Application No. 11/128,556 ("556 application") in view of the "242 patent". Applicant respectfully disagrees with the Examiner's double patenting rejections over the '721, the '051, and the '783 patents at least for the reasons discussed on pages 11-14 of the Amendment dated

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November 30, 2007. In the interest of expediting the prosecution of this application, Applicant acknowledges the Examiner's obviousness-type double patenting rejections and reserves the right to address the double patenting rejections upon allowance of the claims in one of the present application, the '734 application and the '556 application to determine if a Terminal Disclaimer is required at that time.

#### IV. Conclusion

In view of the foregoing remarks, Applicant submits that the claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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